UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,501	08/25/2003	Carl T. Allenspach	PC027523	2375

26648 7590 10/16/2008

PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,501	ALLENSPACH ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-30* is/are pending in the application.

4a) Of the above claim(s) *24-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-23 and 30* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 30 is new. Claim 9 has been cancelled. Claims 1-8 and 10-29 are pending in the application. Claims 24-29 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-8, 10-23 and 30 are under examination as they read upon the elected subject matter. Applicant's amendments have necessitated a new ground of rejection. Accordingly, this action is FINAL.

Claim Objections

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 is still the same composition as claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10-23 and 30 remain/are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Nadkarni et al. (US 2002/0013357 Pub. Date: 01/31/2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Nadkarni et al. disclose pharmaceutical compositions containing from about 1 mg to about 100 mg of valdecoxib useful in treatment of cyclooxygenase-2-mediated conditions and disorders (Abstract). Nadkarni et al. disclose that the tablet compositions contain pregelatinized starch (National Starch 1500: a **corn starch**) in the same amount, 20 mg, as the instant application (Page 8, Tables 1 and 2 and claims 1, 4, 6 and 7). Applicant teaches the same pregelatinized starch in the tablet (instant specification, page 21 Table 1). It is the Examiner's position that since the same pregelatinized starches are taught in the same amount then the tablet disclosed by Nadkarni et al. would have low viscosity and/or exhibit a multimodal particle size distribution and read on instant claims 1-6, 17 and 19. Nadkarni et al. disclose valdecoxib particles have a D_{90} less than about 75 μm (Claim 9) and can be present from about 4 mg to about 40 mg per dose and reads on instant claim 7 (Claim 4). Nadkarni et al. disclose a tablet wherein the excipients comprise one or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, one or more binding agents, starch, is present in an amount of about 0.5% to about 25%, and one or more lubricants in an

amount of about 0.1% to about 10%, by weight of the composition thus anticipating instant claims 20-22 (Claim 5). Nadkarni et al. disclose a tablet wherein the excipients comprise lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch and magnesium stearate thus anticipate instant claim 23 (Claim 7).

Instant claims 9-17 are directed to shear stress values for the pregelatinized starch. Since the disclosure of Nadkarni et al. teaches the exact same pregelatinized starch in the exact same amount as the instant application, then it is the Examiner's position, without evidence to the contrary, that the pregelatinized starch of the disclosure of Nadkarni et al. inherently has those properties. Please note that the Office is not equipped with the proper equipment to test the myriad number of ways an Applicant might measure a variable. When the prior art appears to disclose the same exact components in the same amounts then the burden is shifted to Applicant to demonstrate the difference.

With respect to the USC 102 rejection above, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' pregalatinized starch differs and, if so, to what extent, from that of the discussed reference.

Response to arguments:

Applicant asserts that the cited references are do not teach or suggest using a pregelatinized starch exhibiting the desired shear stress and do not disclose selection of the pregelatinzed starch on the basis of determination of low viscosity and/or a particle size test. Respectfully, the Examiner cannot agree. It appears that the cited prior art uses ***the same*** pregelatinized starch as used by Applicant and, even though Applicant has tediously shown that variability exists with each batch of starch with respect to viscosity and particle size distribution, the claimed limitations are inherent in the prior art composition because the prior art composition includes both low viscosity and bimodal particle size distribution starches. Even Applicant has shown that 4 of 6 batches qualify as low viscosity starches and 8 of 11 exhibited bimodal particle size distribution (remarks page 10, (2)-(3)). The claims as currently amended now read on a product by process. As stated above, the patentability of the product does not depend on its method of production. The Examiner has found a product made with pregelatinized starch that appears to be the same starch as used by Applicant. It is noted that Applicant is also using Starch 1500 supplied by Colorcon (page 21, table 1 [0081]). It appears as if Nadkarni et al. and Applicant are using ***the same*** corn starch and therefore it would have the same properties as claimed by Applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-23 and 30 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Nadkarni et al. (WO 01/41761 A2).

Nadkarni et al. disclose pharmaceutical compositions containing from about 1 mg to about 100 mg of valdecoxib useful in treatment of cyclooxygenase-2-mediated conditions and disorders (Abstract). Nadkarni et al. disclose that the tablet compositions contain pregelatinized starch (National Starch 1500: a **corn starch**) in the same amount, 20 mg, as the instant application (Page 21, Table 1 and claims 1, 4, 6 and 7). Applicant teaches the same pregelatinized starch in the tablet (instant specification, page 21 Table 1). It is the Examiner's position that since the same pregelatinized starches are taught in the same amount then the tablet disclosed by Nadkarni et al. would have low viscosity and/or exhibit a multimodal particle size distribution and read on instant claims 1-6, 17 and 19. Nadkarni et al. disclose valdecoxib particles have a D_{90} less than about 75 μm (Claim 9) and can be present from about 4 mg to about 40 mg per dose and reads on instant claims 7 (Claim 4). Nadkarni et al. disclose a tablet wherein the excipients comprise one or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, one or more binding agents, starch, is present in an amount of about 0.5% to about 25%, and one or more lubricants in an amount of about 0.1% to about 10%, by weight of the composition thus anticipating instant claims 20-22 (Claim 5). Nadkarni et al. disclose a tablet wherein the excipients comprise lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch and magnesium stearate thus anticipated instant claim 23 (Claim 7).

Instant claims 9-17 are directed to shear stress values for the pregelatinized starch. Since the disclosure of Nadkarni et al. teaches the exact same pregelatinized starch in the exact same

amount as the instant application, then it is the Examiner's position, without evidence to the contrary, that the pregelatinized starch of the disclosure of Nadkarni et al. inherently has those properties. Please note that the Office is not equipped with the proper equipment to test the myriad number of ways an Applicant might measure a variable. When the prior art appears to disclose the same exact components in the same amounts then the burden is shifted to Applicant to demonstrate the difference.

With respect to the USC 102/ rejection above, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' pregelatinized starch differs and, if so, to what extent, from that of the discussed reference.

Response to arguments:

Applicant's arguments are the same as above and the Examiner's rebuttal is the same as above except to add in further support of the Examiner's position that Colocorn 1500 is taught by Nadkarni et al. as a pregelatinized starch (page 15, lines 13-14).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst V Arnold
Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616